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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/591,651	02/12/1996	JOHN B. CLASSEN	CLASSEN=1A	9417
1444	7590	06/18/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			LUCAS, ZACHARIAH	
ART UNIT		PAPER NUMBER		
1648		DATE MAILED: 06/18/2004		51)

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	08/591,651	CLASSEN, JOHN B.
	Examiner Zachariah Lucas	Art Unit 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 August 2003.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____.
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Continuation of Disposition of Claims: Claims pending in the application are 5,6,8,10,11,16,27-30,32-41,43,44,46,49-52,55-57,59-68,71-74,77-88 and 90-152.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 5,6,8,10,11,16,27-30,32-41,43,44,46,49-52,55-57,59-68,71-74,77-88 and 90-152.

**DETAILED ACTION**

1. The previous final Office action mailed November 5, 2001 is hereby vacated and prosecution in this application is being reopened for the following reasons. A review of the record in this application reveals that prosecution has twice been closed and that applicant has twice filed Notices of Appeal and Appeal Briefs. After the first Appeal Brief was filed the application was reassigned to a second examiner. That second examiner determined that the application was not properly ripe for appeal as at least one rejection was added to the non-final action of June 20, 2000. Subsequent to this first reopening of prosecution, the second examiner issued the November 5, 2001 final Office action. Applicant responded by filing a proper Appeal Brief on August 8, 2003. Unfortunately, a review of the record indicates that this application is still not ripe for appeal. It is apparent that prosecution in this application is difficult at best in light of a large number of inventions and/or species that were not restricted one from another. As such, both the Office and applicant have missed numerous formality problems in the claims such as claims dependent on cancelled claims and substantive problems such as enablement issues. In order to ensure that the prosecution in this application can be corrected and clarified, the Office deems it necessary to restrict the inventions and species in this application at this time. It is only by taking this action that the Office can ensure that applicant receives a proper and thorough consideration of the elected invention.

Any inconvenience this action may cause applicant is regretted.

2. The Art Unit location of your application, and the examiner to whom the case has been docketed in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Zachariah Lucas in Art Unit 1648.

***Election/Restrictions***

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 5, 6, 8, 10, 11, 16, 27-30, 32-41, 43, 44, 46, 49-52, 55-57, 59-68, 71-74, 77-88, 90-128, and 144-152 drawn to methods of reducing the severity or incidence of an immune disorder, and kits comprising the immunogenic compositions used therein.

Group II, claim(s) 129, drawn to methods for protecting against an infectious disease.

Group III, claim(s) 130-136, drawn to methods of packaging a vaccine.

Group IV, claim(s) 137-143, drawn to methods of developing human vaccines.

4. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: each of the three Groups comprises a separate method for the use of the claimed kits. While the Applicant is entitled to claims directed to a first method of using the claimed compositions, the separate methods are not considered to share a common special technical feature.

***Species Election***

Art Unit: 1648

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The Applicant is required to elect at least one of species (A)-(CCC) as indicated below, and one of species (1)-(7), in addition to the election of one of Groups I-IV.

The species are as follows:

Species (A)-(H) represent the inventions of the elected group wherein the immunogen is one of:

- (A) a viral immunogen;
- (B) a bacterial immunogen;
- (C) a yeast immunogen;
- (D) a mold immunogen;
- (E) a plant immunogen;
- (F) an insect immunogen;
- (G) an allogeneic animal immunogen; or
- (H) a xenogeneic animal immunogen.

If the species of immunogens elected from (A)-(H) above includes any of the immunogens listed as subspecies (I)-(CCC), then the Applicant is additionally required to elect one of those immunogens.

Species (I)-(CCC) represent the inventions of the elected group or species above wherein the immunogen is an immunogen against the indicated pathogen, or the pathogen that causes the indicated disease, selected from the following:

(I)	anthrax;	(S)	dengue;
(J)	plague;	(T)	influenza;
(K)	encephalitis;	(U)	herpes;
(L)	meningitis;	(V)	rabies;
(M)	typhus;	(W)	toxoplasmosis;
(N)	typhoid fever;	(X)	coccidiomycosis;
(O)	Lyme disease;	(Y)	schistosomiasis;
(P)	cholera;	(Z)	malaria;
(Q)	leprosy;	(AA)	Streptococcus;
(R)	varicella;	(BB)	Staphylococcus;

Art Unit: 1648

(CC) Neisseria;	(PP) BCG;
(DD) Escherichia coli;	(QQ) Hemophilus influenza;
(EE) Shigella;	(RR) hepatitis B;
(FF) Leishmania;	(SS) diphtheria;
(GG) cytomegalovirus;	(TT) tetanus;
(HH) respiratory syncytial virus;	(UU) pertussis;
(II) Epstein-Barr virus	(VV) polio;
(JJ) parainfluenza virus;	(WW) measles;
(KK) rotavirus;	(XX) mumps;
(LL) adenovirus;	(YY) rubella;
(MM) human immunodeficiency virus;	(ZZ) influenza;
(NN) hepatitis A virus;	(AAA) cholera;
(OO) Non-A Non-B hepatitis virus (hepatitis C);	(BBB) yellow fever; or
	(CCC) small pox.

Species (1)-(7) represent the inventions of the elected group wherein the immune disorder, the occurrence or severity of which is being reduced, is:

- (1) diabetes;
- (2) systemic lupus erythematosus;
- (3) an immune mediated cancer;
- (4) a rheumatic disease;
- (5) a connective tissue disease;
- (6) a neurological disorder; or
- (7) asthma.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The claims are deemed to correspond to the species listed above in the following manner: The individual species are identified, for example, in claims 5, 77, and 149. The following claim(s) are generic: 27, 32, and 56.

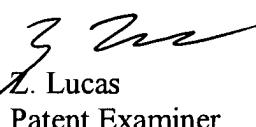
7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species relates either to a different pathogenic immunogen, or to a method of use thereof; or to methods or kits for reducing the incidence or severity of a different immune disorder. In many cases, the method of using said immunogen varies depending on the immunogen elected. The different inventions are therefore deemed to lack a corresponding special technical feature.

### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas

Patent Examiner



JAMES C. HOUSEL

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SUPERVISORY PATENT EXAMINER  
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